UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,213	01/12/2007	Henrike Lotz	P/2107-299	5911

2352 7590 03/03/2010

OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	
MAIL DATE	DELIVERY MODE
03/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,213	LOTZ ET AL.	
	Examiner	Art Unit	
	MARSHA M. TSAY	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-38* is/are pending in the application.

4a) Of the above claim(s) *1-21 and 25-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to Applicants' remarks received December 7, 2009.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim 22 is canceled. Claims 1-21, 25-38 are withdrawn. Claims 23-24 are currently under examination.

Priority: The request for priority to GERMANY 10 2004 013 826.5, filed March 16, 2004, is acknowledged. A certified copy of the foreign priority document has been filed in this case on 9/15/06 and is in a non-English language.

Objections and Rejections

Claim 24 is objected to because of the following informalities: claim 24 is drawn to a pharmaceutical composition comprising an agent selected from the group consisting of (1) to (4), respectively. The claim is objected to because there is nothing in the composition to identify it as a pharmaceutical composition, i.e. a "pharmaceutical carrier" is not currently recited in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions comprising an agent selected from the group consisting of (1) to (4). The group members (1)(c) to (1)(d) in claims 23-24 recite nucleic acid fragments and derivatives thereof of instant SEQ ID NO: 1. *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." As stated above, nucleic acid fragments and derivatives thereof of instant SEQ ID NO: 1. However, the skilled artisan cannot necessarily envision the detailed structures of ALL of the derivatives and or fragments of instant SEQ ID NO: 1 that have the same functional activity as wild-type SEQ ID NO: 1 because nowhere in the specification is it described which amino acids are even essential and critical for the wild-type protein to maintain its functionality, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is

required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The previous 35 U.S.C. 112, first paragraph, scope of enablement and written description rejections have been withdrawn in view of Applicants remarks received December 7, 2009.

However, claims 23-24, parts (1)(c) to (1)(e), are rejected under 35 U.S.C., first paragraph, for the reasons noted above.

In their remarks received December 7, 2009, Applicants assert homologues and fragments of nucleic acids, according to subparagraphs (c) and (e) in paragraph 1 of claims 23 and 24 can readily be determined by one having ordinary skill in this field without the need to undertake any undue experimentation. Applicants submit that, at the time the invention as now claimed was made, it was a routine matter for one having ordinary level of skill in the relevant field to test the specific 'category' of nucleic acids recited in subparagraphs (c) and (e) in paragraph 1 of claims 23 and 24 using high through-put techniques that were well known to those working in this field at the relevant time. Applicant's arguments have been fully considered but they are not persuasive.

Claims 23-24, parts (1)(c) to (1)(e), are claiming derivatives and fragments of SEQ ID NO: 1, as well as derivatives and fragments of the complementary strand of SEQ ID NO: 1, with the ability to encode a cell wall protein necessary for the hyphae development of a pathogenic fungal organism. Applicants have not provided any examples of the nucleic acids covered by claims 23-24, parts (1)(c) to (1)(e) and/or the testing and/or experiments that need to be performed in order to determine if they are able to encode a cell wall protein necessary for the

hyphae development of a pathogenic fungal organism. It is known in the art that an amino acid sequence identity of 50% does not guarantee structural similarity (Yuan et al. 1998 Proteins 30: 136-143), and that even a single point mutation in a polypeptide sequence can lead to surprising alterations in protein structure and activity (Sergel et al. 2000 J Virol 74: 5101-5107).

Thus, Applicants were not in possession of the claimed genus of derivatives and fragments of SEQ ID NO: 1. Applicants are directed to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, § 1 Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24 remain rejected under 35 U.S.C. 102(a) as being anticipated by Lotz et al. (2004 Eukaryotic Cell 3(3): 776-784; previously cited). For examination purposes, claims 23-24 have been interpreted as an agent selected from the group consisting of (1) to (4), since there are no additional components or limitations recited in the instant claims.

Lotz et al. teach a method comprising using DNA microarray analysis to identify RIM101-regulated cell wall genes in C. albicans (p. 778, columns 1-2). The method of Lotz uses a DNA microarray comprising orf6.647 to measure the amount of hybridizing orf6.647 mRNA in wild-type *C. albicans* and a mutant *C. albicans* RIM101 knockout (p. 777, column 2). On

pages 10 and 60 of the instant specification, SEQ ID NOS: 1 and 2 are alternatively referred to as Rbr1p, Rbr1, and orf6.6747. This anticipates claims 23-24 as written.

Should Applicant present an argument that the reference of Lotz et al. cannot be applied in a rejection under 35 U.S.C. 102(a) due to the date of the publication, Applicant should provide an English translation of the priority document submitted with the instant application.

In their remarks, Applicants assert Applicants respectfully submit, however that the Lotz publication is not an effective reference against the claims of their application. That is, the Lotz et al. reference has a publication date of June 2004. In contrast, the present application is a §371 National Stage filing of PCT/EP2005/002748 (filed January 16, 2006) which, in turn, claims the priority of 'parent' German application No. 102004013826.5 filed on March 16, 2004, i.e., a date which is prior to the publication date of the Lotz et al. reference.

Further with regard to applicants' claim for priority, p. 3 of the Office Action acknowledges the claim and states that a certified copy of the foreign (German) priority document was filed in this case on September 15, 2006. However, the copy is in a non-English language, i.e., German. Thus, at p. 11 of the Office Action the Examiner further states that should applicants present an argument, which they in fact are presenting, that the reference of Lotz et al. cannot be applied in a rejection under 35 U.S.C. 102(a) due to the date of the publication, applicants should provide an English translation of the priority document submitted with the instant application.

In response, applicants note for the Examiner's information that the priority document (i.e., German application No. 102004013826.5) has the same wording, i.e., without any

additions, deletions or modifications as the International Application (PCT/EP200510903947) which forms the basis for the present U.S. national filing. The present U.S. application thus differs from the priority document (German 102004013826.5) on_q_nJ21 with regard to the amendments set forth in the Preliminary Amendment filed on September 15, 2006 with the present application. In effect, therefore, applicants submit that they have already provided what amounts to an English translation of the priority document submitted with the instant application. Thus, they believe that they are already in compliance with the Examiner's requirement for a translation of the priority document. Applicant's arguments have been fully considered but they are not persuasive.

Response: Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

See also MPEP 2304.01(c).

Claims 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsong et al. (2003 Cell 115(4): 389-399; pdf copy is provided, previously cited). Tsong et al. teach a table of C. Albicans genes that were identified by microarray analysis (p. 14 of pdf copy), including orf.6.6747 (p. 62 of pdf copy). Therefore, Tsong et al. teach orf.6.6747. On pages 10 and 60 of the instant specification, SEQ ID NOS: 1 and 2 are alternatively referred to as Rbr1p, Rbr1, and orf6.6747. This anticipates claims 23-24 as written.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARSHA M. TSAY whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 25, 2010

M. Tsay
Art Unit 1656

/Manjunath N. Rao /
Supervisory Patent Examiner, Art Unit 1656